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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/262,126

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BRIAN S. MILLER

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ATTENTION: LEGAL DEPARTMENT
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EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

04/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/262,126	Applicant(s) MILLER ET AL.	
	Examiner Rosanne Kosson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 12, 14, 15, 27-40 and 52-73 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 14, 15, 27-40 and 52-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse of Group 1, claims 5-10, 14, 15, 27-40 and 52-73 in the reply filed on February 29, 2008 is acknowledged. Claim 12 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. In response to Applicants' comments on the restriction requirement Office action, before this Office action, the present Examiner had not searched or examined either invention, and the previous Examiner did not search Group 2 separately. A separate and different search for this group and a new, separate and different examination are required. As for the pullulanase fragments claimed in Group 1, as discussed below, claim limitations of deletions of up to about 300 amino acids are deletions of one to about 300 amino acids.

The amendment filed on December 19, 2007 has been received and entered. Claims 5, 27 and 36 have been amended. Claims 1-4, 11, 13, 16-26 and 41-51 have been canceled. Claims 67-73 have been added. Accordingly, claims 5-10, 14, 15, 27-40 and 52-73 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In view of Applicants' amendment to claim 5, the objection in the previous Office action is withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-10, 14, 15, 27-40 and 52-73 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read on products of nature and do not reflect the hand of man, i.e., that these are articles of manufacture (see MPEP §706.03). The claims recite naturally occurring proteins, naturally occurring proteolytic fragments of a full-length pullulanase from *Bacillus deramificans* (see pp. 6-9 of the specification). The claims may be amended to recite that the claimed protein fragments are purified or isolated. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 15 and 67-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fragment of a pullulanase that is encoded by the DNA of SEQ ID NO:1 and that is shorter than the encoded protein by 98, 100 or 102 amino acids, does not reasonably provide enablement for a fragment of a pullulanase that is encoded by a polynucleotide having 90% sequence identity to the DNA of SEQ ID NO:1 and that is shorter than the encoded protein by 98, 100 or 102 amino acids (recited in the claims as "about 100" amino acids). As a result, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether or not undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir.1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in

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successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

Factors pertinent to this discussion include the predictability of the art, guidance in the specification, the breadth of claims and the amount of experimentation that would be necessary to use the invention.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for vast numbers of multiple substitutions and/or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein, the result of which is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, *e.g.* multiple substitutions. SEQ ID NO:1 is a very long DNA sequence (2794 nucleotides), and although Fig. 1 discloses several loci of 2-5 amino acids that should be retained for function, the number of mutations (substitutions, deletions, insertions and/or chemical derivitizations) encompassed by the claims is extremely large, 279 nucleotide positions.

The specification does not support the broad scope of the claims which encompass a protein encoded by a DNA having at least 90% sequence identity to SEQ ID NO:1, because the specification does **not** establish: (A) regions of the protein structure which may be modified without affecting pullulanase activity, including the amino acid positions that make up the

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catalytic or substrate binding site; (B) the general tolerance of pullulanases, in particular *Bacillus deramificans* pullulanase, to modification and the extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices are likely to be successful.

Without sufficient guidance, beyond that provided, obtaining a DNA having at least 90% identity to SEQ ID NO:1 is unpredictable, and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a protein encoded by a polynucleotide having 90% sequence identity to SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

In view of the foregoing, the claims fail to satisfy the enablement requirement.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10, 14, 15, 27-40 and 52-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8, 14, 15, 27-30, 33-40, 52-57 and 60-71 recite a truncated pullulanase in which "about 100" or "about 200" or "about 300" amino acids have been deleted. These terms are not defined in the specification, rendering the metes and bounds of the claims unclear. It

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cannot be determined how many amino acids "about 100," "about 200" and "about 300" are. Appropriate correction is required. The word about may be deleted or a set of definite numbers may be recited.

Claims 6-8 and 27-30, 60-62 recite a *Bacillus deramificans* pullulanase having an N-terminal deletion of about 100, 200 or 300 amino acids, but no reference sequence is provided. Claims 9, 10, 58 and 59 recite a *Bacillus deramificans* pullulanase having an N-terminal deletion of 98 or 102 amino acids, but no reference sequence is provided. That is, the claims recite a pullulanase fragment that is shorter by an indefinite amount than a particular pullulanase, but the claims do not recite what that longer pullulanase is. If the length of the longer pullulanase is not known, the length of the shorter pullulanase cannot be determined, even if definite deletions were recited. If the reference sequence is not known, the nature of what is deleted and what is conserved is not known. Thus, the meaning of the claims is unclear, and the metes and bounds of the claims cannot be determined. Appropriate correction is required. The claims should recite a reference sequence, e.g., SEQ ID NO:2.

Claims 39 and 40 are indefinite, initially, because they are ambiguous and their intended meaning cannot be determined. They recite in one meaning that the pullulanase of claim 27 is truncated by at least 60% or at least 80% respectively. First, at least 60% and at least 80% truncation read on 60-100% and 80-100% truncation. There may nothing left at all but the conserved Y position (YY) and the catalytic site, and the size and the nature of the protein fragment of claim 27 are not known. Consequently, deleting at least 60-80% of an unknown protein produces a smaller protein that is more unknown in size, structure and function. It cannot be determined that a truncated pullulanase that is the result of deleting, first, "about" 100-300 amino acids and then another at least 60-80% from any one or from any number of regions of the fragment of the first truncation is a functional pullulanase or a molecule that has

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any function or activity at all. In the second potential meaning, the claims recite a composition of a truncated pullulanase in which the composition comprises at least 60%, or at least 80%, truncated pullulanase, i.e., the % by weight of the pullulanase compared to the other components in the composition. But, it cannot be determined if this second interpretation is what Applicants mean to recite. Appropriate correction and clarification are required.

Claims 31 and 32 recite that amino acids 99 and 103 of SEQ ID NO:2 are E. The sequence listing shows that amino acids 99 and 103 are K and A, respectively. Thus, the claims are confusing. Appropriate correction is required. The claims may be amended to match the sequence listing.

Claims 5, 58 and 59 contain abbreviations that should be written in full so that the meaning of the claims is clear. The phrase "the designation T89.117D in the LMG culture collection" may be amended to "the biological deposit number T89.117D in the Belgian Coordinated Collections of Microorganisms at the University of Ghent, Laboratory of Microbiology (LMG culture collection)."

Claims 52-57 and 70-73 are indefinite because they are confusing with respect to their recitation of SEQ ID NO:2 in a fashion that implies that it is the mature pullulanase from which all the deletions are made (the 927-amino acid form). SEQ ID NO:2, however, is not the mature pullulanase. It is the full-length form containing the secretion signal (956 amino acids). Appropriate correction is required. These claims may be amended to refer to the mature form of the pullulanase of SEQ ID NO:2.

In claims 60-64 recite that the pullulanase fragment further comprises four more amino acids, VWAP. It cannot be determined if Applicants' meaning is that the fragments recited in these claims are four amino acids longer than the fragments recited in the claims from which these depend (claims 6-8, 14 and 27) or if the meaning is that these four amino acids are a part

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of the fragments recited in claims 6-8, 14 and 27. Appropriate clarification and correction are required.

The Markush group in claim 65 requires correction. The conjunctions "or" or "and/or" may not be used to conclude a Markush group and should be deleted. Classes or types of enzymes are recited, not individual enzymes. Thus the article "a" or "an" should be placed before the listed members. The claim may be amended to recite that the composition further comprises an enzyme selected from the group consisting of a glucoamylase, ... an isoamylase, ... and an enzyme that cleaves glucosidic bonds. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 27-30, 33-40, 55 and 64 are rejected under 35 U.S.C. 102(a) as being anticipated by Deweer et al. (US 5,721,128). These claims recite a composition comprising a truncated pullulanase from which up to about 100-300 amino acids have been deleted from the N-terminus. This limitation corresponds to a deletion of 1 to about 300 amino acids from the N-terminus. Deweer et al. disclose SEQ ID NO:1 (labeled SEQ ID NO:10) and the encoded polypeptide (labeled SEQ ID NO:11), a fragment of instant SEQ ID NO:2 having the first 29 amino acids of SEQ ID NO:2 deleted, the mature form of this pullulanase. Deweer et al. also disclose the heat and acid stability of this truncated enzyme and the *Bacillus licheniformis* strain that makes the enzyme (see col. 1, line 43, to col. 2, line 25; and col. 5, lines 20-28). Deweer et al. disclose that their mature pullulanase may be modified by at least one amino acid via

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conventional molecular biology techniques (see col. 5, line 49, to col. 6, line 8). Modifications by conventional molecular biology techniques include deletions, additions and substitutions, which encompass deletions of one or more amino acids. Deweer et al. disclose liquid or solid compositions for digesting starch comprising their SEQ ID NO:11 and a second enzyme, e.g., an amylase or glucosidase, or a glucoamylase from *Aspergillus* and that a two-enzyme composition may contain at least 60%, i.e., 60—>99% of the modified truncated pullulanase (see col. 3, line 57, to col. 4, line 15; and col. 8).

In view of the foregoing, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

Claims 5-8, 14, 15, 27-40 and 52-57 and 60-66 are again rejected and claims 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deweer et al. (US 5,721,128, filed on Jun. 7, 1995 and issued on Feb. 24, 1998), McPherson et al. (Biochemical Soc Trans 1988, 16(5):723-724, 1998) and Albertson et al. (Biochim Biophys Acta 1354:35-39, 1997). This rejection has been discussed in the previous Office actions.

Applicants have not presented any new arguments but reassert their previous arguments. Applicants assert that Deweer et al., US 6,074,854, are not available as prior art, because the dates of this patent put it in the category of prior art that would be available under §102(e) only, and, because this patent and the instant application are commonly owned, the patent is not prior art under § 103(c)(1). In reply, US 6,074,854 is not available as prior art. But, US 5,721,128, also issued to Deweer et al., is prior art with dates corresponding to the §102(a) category, as it was published before the instant priority date, and the inventors of this patent, Messrs. Deweer and Amory, are a different inventive entity than the instant inventors, B. Miller and J. Shetty. Thus, Deweer et al., US 5,721,128, is a disclosure by another that was published

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before the effective filing date of the instant application and is prior art.

To reiterate, Deweer et al. disclose SEQ ID NO:1 (labeled SEQ ID NO:10) and the encoded polypeptide (labeled SEQ ID NO:11), a fragment of instant SEQ ID NO:2 having the first 29 amino acids of SEQ ID NO:2 deleted, the mature form of this pullulanase. Deweer et al. also disclose the heat and acid stability of this truncated enzyme and the *Bacillus licheniformis* strain that makes the enzyme (see col. 1, line 43, to col. 2, line 25; and col. 5, lines 20-28). Deweer et al. disclose liquid or solid compositions for digesting starch comprising their SEQ ID NO:11 and a second enzyme, e.g., an amylase or glucosidase, or a glucoamylase from *Aspergillus* (see col. 3, line 57, to col. 4, line 15; and col. 8).

McPherson et al. disclose that pullulanases are very large enzymes compared to other polysaccharide hydrolases and that this large size creates steric hindrance which reduces the efficiency with which they can cleave internal alpha-1,6 bonds in highly branched substrates (see p. 723, left col.). McPherson et al. disclose that pullulanases in a wide variety of bacteria and fungi do not share a high degree of overall amino acid sequence identity. But, they do share conserved sequences in their C-terminal halves, where the enzymatic activity resides, the N-terminal region is not required for enzymatic activity, and experiments with pullulanases from a variety of microorganisms are underway to determine how much of the N-terminus may be deleted with the retention of activity. One example is provided in which the deletion of 170 amino acids from the N-terminus lead to a 30% increase in activity relative to the native enzyme (see p. 723, right col.). Thus, as "about 200" is not defined in the specification, McPherson et al. disclose a pullulanase fragment having about 200 amino acids deleted from the N-terminus.

Albertson et al. disclose that the four highly conserved regions of pullulanases are in the central and C-terminal portions, while the N-terminal portions vary in length and are not required for function. Albertson et al. also disclose a pullulanase truncation fragment having an N-

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terminal deletion of 381 bp, or 127 amino acids (see abstract). A polynucleotide referred to as NZ1452 encodes a pullulanase having an N-terminal 95-amino acid deletion relative to the wild type with the retention of function (see p. 38). Thus, as "about 100" is not defined in the specification, Albertson et al. disclose pullulanase fragments having about 100 amino acids deleted from the N-terminus.

It would have been obvious to one of ordinary skill in the art at the time that the invention was made to prepare a pullulanase having an N-terminal deletion of about 100-200 amino acids, because McPherson et al. and Albertson et al. teach that the N-terminus of a pullulanase is not required for function and causes steric hindrance, which decreases enzymatic activity. All three references teach that pullulanases are large enzymes, i.e., the DNA and amino acid sequences are long relative to other enzymes. One of ordinary skill in the art would have known that it is easier to clone smaller genes than larger genes, that is, that reducing the length of the DNA would have made the gene easier to clone, and that larger proteins are more difficult to produce recombinantly than smaller proteins, particularly for secreted proteins, because they are more likely interfere with the health of the recombinant host cell and are more difficult to secrete. Additionally, "about 300" amino acids is not defined in the specification, and the prior art teaches that pullulanases, including their N-terminal portions, are large and that the enzymatic function resides in the C-terminal portion or middle of the molecule. As a result, one of ordinary skill in the art would have reasonably expected to have been able to delete more than 200 amino acids, in particular, about 300 amino acids, from the N-terminus of a pullulanase that is greater than 900 amino acids in length with the retention of function.

In view of the foregoing, a holding of obviousness is required.

Double Patenting

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Claims 5-10, 14, 15, 27-30, 33-40 and 52-66 are again rejected and claims 67-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4 and 6-11 of Deweer et al., U.S. Patent No. 6,074,854, either alone or in view of McPherson et al. and Albertson et al. This rejection has been discussed in the previous Office actions.

Applicants assert that Deweer et al. disclose different pullulanase fragments than those recited in the claims, i.e., fragments having 1 – about 300 amino acids deleted from the N-terminus [or the mature form having the addition of an N-terminal A]. Applicants assert that McPherson et al. and Albertson et al. disclose pullulanases from different bacteria having different sequences than instant SEQ ID NO:2 and that these references are not relevant, because Deweer et al. do not disclose the claimed fragments.

In reply, the claims of Deweer et al. anticipate the instant claims, because they recite that the pullulanase may be made by a derivative of *Bacillus deramificans*, which reads on a mutant strain in which the pullulanase gene has been modified in any way, including by deletions that yield a truncated enzyme. Claim 3 of Deweer et al. recites that the enzyme may be modified in any way as long as its activity is retained. As discussed previously and above, McPherson et al. and Albertson et al. are relevant, because they disclose that the enzymatic activity does not reside in the N-terminal portion, and that removing this portion may enhance enzymatic activity, because this portion causes steric hindrance in acting on the substrate, due to the great size of the enzyme.

Claims 5-10, 14, 15, 27-30, 33-40 and 52-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6 of Deweer et al., U.S. Patent No. 5,721,127, either alone or in view of McPherson et al. and Albertson et al. This rejection is similar to the one above.

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Applicants assert that Deweer et al. disclose different pullulanase fragments than those recited in the claims, i.e., fragments having 1 – about 300 amino acids deleted from the N-terminus [or the mature form having the addition of an N-terminal A]. Applicants assert that McPherson et al. and Albertson et al. disclose pullulanases from different bacteria having different sequences than instant SEQ ID NO:2 and that these references are not relevant, because Deweer et al. do not disclose the claimed fragments.

Claims 5-6 of Deweer et al. anticipate the instant claims, because they recite that the pullulanase may be made by a strain of *Bacillus deramificans* having a modified version of their SEQ ID NO:10 (instant SEQ ID NO:1), which reads on a mutant strain in which the pullulanase gene has been modified in any way, including by deletions that yield a truncated enzyme, as long as the encoded enzyme retains its activity. As discussed previously and above, McPherson et al. and Albertson et al. disclose that the enzymatic activity does not reside in the N-terminal portion, and that removing this portion may enhance enzymatic activity, because this portion causes steric hindrance in acting on the substrate, due to the great size of the enzyme. Thus, it would have been an obvious modification to make deletions from the N-terminus that do not decrease enzymatic activity.

In view of the foregoing, the rejection of record is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the

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organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Art Unit 1652

rk/2008-04-01

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652